UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,335	12/21/2001	Sivaram Pillarisetti	18631-0121 (45115-264494)	1157

26158 7590 11/08/2004

WOMBLE CARLYLE SANDRIDGE & RICE, PLLC
P.O. BOX 7037
ATLANTA, GA 30357-0037

EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,335	PILLARISETTI ET AL.	
	Examiner	Art Unit	
	David A Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,10-14 and 16-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-6,10-14 and 16-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Art Unit and the examiner for this application have changed; see closing paragraphs for contact phone numbers.

The amendment of 6/29/04 has been entered. Claims 1-6, 8-14 and 16-34 are pending.

Applicant's election without traverse of Group I (claims 1-6, 10-14 and 18-34) in the reply filed on filed 6/29/04 is acknowledged.

Upon reconsideration it is considered that the election /restriction requirement mailed on 5/25/04 should be restated, since the method of detecting compounds and the method of treating inflammation are not species of one invention but, rather, separate inventions and would not be subject to rejoinder.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 10-14 and 27-34, drawn to methods of delecting compounds/ compositions that affect inflammation / glycated protein accumulation, classified in class 435, subclass 4+ and class 436, subclass 86.

II. Claims 8-9 and 16-17, drawn to compositions that affect inflammation/glycated protein accumulation, classified in class 424, subclass 78.05 and 85.1 – 780 and class 514, subclass 1-789 and 886.

III. Claims 18-26, drawn to methods for treating inflammation, classified in class 424, subclass 78.05 and 85.1-780 and class 514, subclass 1-789 and 886.

The inventions are distinct, each from the other because:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the compounds/ compositions of Group II are not related to the screening/ detecting method of Group I in any material way. That is, the compositions are not synthesized or purified by the method of Group I. Rather, the screening / detecting method of Group I merely further characterizes the inherent properties of an already provided compound / composition (e.g. anything from an inorganic salt to a complex extract of a tree bark). As such the products of Group II have an existence independent of the screening/ detecting method of Group I and must be searched separately.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case compounds/ compositions to be used in the treatment method of Group III are not related to the screening / detecting method of Group I in any material way. As noted in the above paragraph regarding groups I and II, the method of Group I merely further characterizes inherent properties of an already provided compound / composition. Furthermore compounds to be used in the treatment method of Group III could have already be identified by other methods of identifying anti-inflammatory drugs (e.g. using animal models) and used in treatments. The screening detecting method of Group I would merely further characterize inherent properties of known drugs. Since

the treatment method of Group III can exist independently from the screening / detecting method of Group I, the method of Group III must be search separately.

Inventions Group II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, as noted in the paragraphs supra, the compounds/ compositions of Group II have an existence that is independent of their characterized properties and independent of any clinical trials that would be required to treat inflammation. Therefore the search for the compositions of Group II must be conducted separately.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Note that if Group III could be rejoined with Group II, if Group II were to be found allowable. In re Ochia 37 USPQ2d 1127.

Irrespective of what group might be elected the following election of species is required.

Claims 1, 10, 23, 27 and their dependents are generic to a plurality of disclosed patentably distinct species comprising the determinants (markers) of inflammation recited as part c) of each of these claims. These markers do not have a common core structure and are art recognized as having different functions. In re Harnish 206 USPQ

300. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In the event Group I is elected, the examiner will not require an election of species with respect to the members recited in claims 4, 13 or 28. It is the nature of screening asays that they be used to identify the inherent activities of a large number and divergent types of compounds/ compositions.

In the event that Group II or III is elected the following additional election of species is required.

Claims 8, 16, 18, 23 and their dependents are generic to a plurality of disclosed patentably distinct species comprising the compounds recited in each of claims 4, 13 and 28. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 / 614

Saunders/LR
October 1, 2004